# LEAK POINT WETNESS SENSOR FOR UROLOGICAL INVESTIGATIONS

## Specification

### Field of the Invention

For use in urological investigations of the female bladder and urethra, a detector responsive to leakage of liquid from the urethra.

### Background of the Invention

Urologists and other physicians are interested in learning when and under what conditions leakage from urethra first occurs during an investigation of the bladder and urethra. In the course of the investigation, liquid is forced into the bladder through a catheter, and the pressure and the amount of liquid (urine and water) is known. The patient is asked to assume a number of positions, and to make various exertions, such as muscular contraction and coughing. In the course of these events, liquid will at times and under certain circumstances leak past the catheter. The conditions under which this leakage just begins is of importance to the physician in his investigation of the bladder and urethra.

While leakage can be visually detected, the relationship of its exact time of occurrence with respect to other measured parameters during a urodynamic procedure is critical for the proper evaluation of the test data. It is an object of this invention to provide a simple and rugged sensor and related

circuity which will inform the urologist of the event of leakage, and if desired will also record the relative time and conditions under which it occurred, all without immediate attention by the physician.

A sensor to detect and notify of leakage past the urethra is disclosed in Ketchum patent No. 5,862,804, which does in fact detect such leakage, relying on a difference between ambient (room) temperature and the temperature of the leaked liquid. This instant invention, by the same inventor, is intended to provide optional or less complex references and measurements for the same purposes.

Brief Description of the Invention

A sensor according to this invention, including its reference and temperature responsive circuity, detects wetness by measuring the temperature of a liquid which contacts it. It is an advantage of this invention that the sensor responds quickly to the temperature of the liquid, but drains and dries quickly so as to be sensitive to next events, such as leakage caused by successive, relatively rapid coughs without being masked by the previous event.

It is an object of this invention to simplify the sensor system shown in the Ketchum patent in order to reduce its cost and also to reduce the number of comparative measurements which need to be made in order to detect the liquid.

In its every embodiment the sensor functions by sensing the temperature which is respective to liquid expelled from the urethra. It should be observed that this instrument surrounds a catheter which is inserted into the bladder through the urethra. The instrument is held immediately adjacent to the urethra. The liquid when it reaches the sensor will have leaked past the catheter and will be at or very near to body temperature. This temperature will invariably be higher than ambient, and higher than any other temperature likely to be encountered by the instrument.

Accordingly, in one embodiment of this invention, instead of using the output from a sensor responding to ambient temperature, a reference circuit provides a generated output simulative of some temperature sufficiently lower than the output of a sensor that is responsive to temperature of the liquid. Then only one sensor is needed. This can greatly simplify the instrument, and will reduce its cost and complexity.

In another embodiment of the invention, the rate of rise of the temperature where the liquid is to be detected can be used. A sufficient rate of rise would not be occasioned merely by a change in room temperature, which would be gradual. Instead it would be caused by contact with a warm liquid. A sufficient rate of rise will correctly reflect contact with a liquid at a sufficient temperature.

The above and other features of this invention will be fully understood from the following detailed description and the accompanying drawings, in which:

Brief Description of the Drawings

Fig. 1 is an axial cross-section of the preferred embodiment of a wetness sensor according to the invention;

Fig. 2 is an axial cross-section taken at line 2-2 in Fig. 1;

Fig. 3 is an end view taken at line 3-3 in Fig. 2;

Fig. 4 is a schematic circuit drawing of another embodiment of the invention; and

Fig. 5 is a schematic circuit drawing of yet another embodiment of the invention.

Detailed Description of the Invention

A leak point detector 10 according to the invention is shown in Figs. 1-3. Its body 11 may have any desired external configuration, from a single cylindrical shape to one which is shaped for a better grip. A passage 12 passes a catheter 13.

The catheter is a tube having an internal lumen 14 through which liquid, usually water or a saline solution, is passed into the bladder. The proximal end 15 of the catheter is connected to a source of liquid (not shown). The distal end 16 of the catheter is passed through the urethra into the bladder. Leakage to be detected will flow between the urethral wall and the

external wall 17 of the catheter when the urethra is no longer able to prevent the leakage.

Catheter wall 17 makes a close fit with wall 18 of passage 12 at its proximal end 19. Passage 12 is expanded at the distal end 20 of the body to form a receptacle 21. Drain channels 22 extend from the receptacle to the exterior of the body so as to drain liquid that flows into the receptacle. There is no intention or purpose to collect the liquid, and it must promptly be drained for a reason yet to be disclosed.

A temperature sensitive detector sensor 28 is bonded to the wall 29 of the receptacle by a layer 30 of cement. The detector is exposed so as to be contacted by liquid which has leaked from the patient. It is also exposed to ambient temperature through the drain channels.

According to one embodiment of the invention, shown in Fig. 4, the signal from detector sensor 28 is provided through leads 31 to a comparator 32. This signal is, for example, a voltage proportional and respective to the temperature of the sensor-that is, the temperature measured of leaked liquid that contacts it. When dry, the signal merely reflects what is around it, usually ambient air. When wetted, it will be the temperature of the liquid expelled from the urethra, which will always be higher than ambient.

A circuit 33 acts as a signal generator which generates and

provides a signal, usually a voltage, simulative of some lower temperature than would be expected from the liquid. It will usually be proportional to ambient. Its setting is preferably, but not necessarily adjustable, but it is not temperature responsive. Instead it is non-reactive and will ordinarily be set to produce a voltage respective to a simulated temperature somewhat greater than ambient, but less than that of leaked liquid. There always will be a difference between the two signals, so the comparator will be adjusted to provide no output signal of its own when the sensor is dry. Then, when the sensor is wetted by warm liquid, the comparator will have been set to respond when the sensor temperature increases by some arbitrary number of degrees above the simulated temperature, perhaps 10 degrees.

The signal from the comparator is provided to a recorder 35 and to a signal 36. Obtaining this signal is the objective. It states the event of leakage. The actual temperature of the leaked liquid is immaterial.

The second embodiment, shown in Fig. 5, does not respond to any specific temperature. Rather it responds to rate of change of temperature. Thus, gradual changes in room temperature, and changes in the temperature of the body of the instrument itself are ignored by it. However, when leaked liquid at an elevated temperature contacts the sensor, there will be a rapid rise of

temperature at the sensor, which is uniquely indicative of the presence of the warm liquid.

For this purpose, the signal from detector sensor 28 is provided to a rate of change detector 40. This will react to a change of the sensor output respective to a quick rise in temperature. A typical differentiating circuit will perform this task, and no specific description is required for an understanding of the invention. A required rate of rise can readily be determined, and the detector can be adjusted to that level, both by brief observation of the existing circumstances. Detector 40 provides its signal to a recorder 41 and/or a signal 42. It stops its signal when the temperature falls, so as to be ready for the next liquid. It will be observed that there is no source of a simulated temperature for comparison purposes. No comparison is made. Only the abrupt rise occasioned by the leaked fluid is detected.

In the procedure, the catheter is first passed into the bladder through the urethra. Then to position the wetness sensor on the catheter, the proximal end of the catheter is either passed through the passage 12, or is clamped around the catheter depending on the particular design of the wetness sensor. In either case, when it is placed at a desired location along the catheter, a plunger 44, or other friction device will be set to bear against the catheter so the body cannot slide along the

catheter. The plunger, or other friction device, may be spring-driven, threaded, or otherwise mounted as desired for this purpose.

A thermistor is the preferred example of a temperature sensing element for use in this device. Its surface is resistant to water and to urine, and it is sensitive to small changes of temperature. Its resistance decreases with increasing temperature. However, other types of temperature sensors, including direct-reading electronic thermometers may be used instead. Therefore the thermistor is referred to generally as a temperature sensitive element, but it is the preferred device.

In use, leakage liquid generally first flows slowly, drop-by-drop as shown in the Fig. 1 as drops 50. They flow along the surface of the catheter to the narrowed part of the receptacle, where they contact the detector sensor. Then they flow out through the drain channels so the thermistor can drain dry again and be ready for the next drops. It is undesirable for the detector thermistor to remain in continuous contact with the liquid, because this would frustrate the comparison between the temperature of freshly-received liquid and the ambient temperature, and would prevent intermittent flows from being sensed.

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This invention is not to be limited by the embodiments shown in the drawings and described in the description, which are given by way of example and not of limitation, but only in accordance with the scope of the appended claims.